

HFI-35749
721

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: 1177865

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

December 17, 1997

ADDENDUM TO WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ira D. Godwin, M.D., Director of Laboratories
American Medical Laboratories, Incorporated
14225 Newbrook Drive
Chantilly, Virginia 22021-0841

Dear Dr. Godwin:

This letter is being written as an addendum to the Warning Letter dated December 9, 1997, received at your facility on December 12, 1997, to clarify the timeframe for the review of anti-HIV-1 Western Blot confirmatory test results.

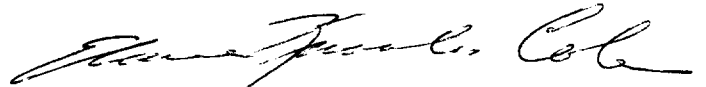
Please be advised that the Food and Drug Administration requests that your facility expand the review of anti-HIV-1 Western Blot confirmatory test results to the point in time at which you began the procedure of repeating Western Blots on samples testing "indeterminate" and changing the "indeterminate" result to "negative" if the retest was "negative." This is not in accordance with the manufacturer's test kit instructions.

As previously stated in the December 9, 1997 Warning Letter, we request that you notify all facilities that submitted donor samples to your firm for anti-HIV-1 Western Blot confirmatory testing that were initially found to be "indeterminate," but were retested and reported as "negative" for the timeframe stated above, that the results were changed. In addition, please provide the names of the facilities identified during your

Dr. Ira D. Godwin
Page 2
December 17, 1997

review to Mr. Wiley T. Williamson, III, Compliance Officer, Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201. Mr. Williamson can be reached at 410-962-4366, Extension 136.

Sincerely,

A handwritten signature in cursive script, appearing to read "Elaine Knowles Cole".

Elaine Knowles Cole
Director, Baltimore District

cc: Ms. Judith Yost
Health Care Financing Administration
Division of Outcomes and Improvements
7500 Security Boulevard
52-11-07
Baltimore, Maryland 21244-1850